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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,113	11/01/2005	Shinji Nakade	Q85522	9389
65565	7590	09/01/2009	EXAMINER	
SUGHRUE-265550			RICCI, CRAIG D	
2100 PENNSYLVANIA AVE. NW			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20037-3213			1614	
			MAIL DATE	DELIVERY MODE
			09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/519,113	NAKADE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 09 July 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-65 is/are pending in the application.  
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 10-16,44,46,47,55,57 and 58 is/are rejected.  
 7) Claim(s) 17,20,22,25,27,29,30,51 and 52 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

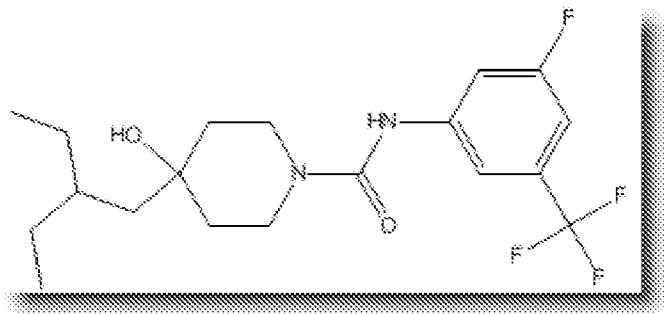
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>12/23/2004 and 3/31/2005</u> .	6) <input type="checkbox"/> Other: _____ .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-9,18,19,21,23,24,26,28,31-43,45,48,50,53,54,56 and 59-65.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election **without** traverse of Group I in the reply filed on 7/09/2009 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 1-9 and 61-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/09/2009.
3. Applicant's election **without** traverse of the following compound species is also



acknowledged:

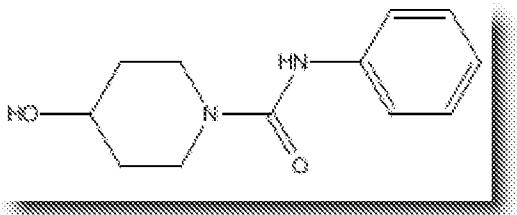
Applicants indicate that the elected species reads upon claims 10-16, 44, 46-47, 55, 57-58 and 60. However, it appears that the elected species actually reads upon claims 10-17, 20, 22, 25, 27, 29-30, 44, 46-47, 49, 51-52, 55 and 57-58. As such, claims 18-19, 21, 23-24, 26, 28, 31-43, 45, 48, 50, 53-54, 56, and 59-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/09/2009.

### *Claim Objections*

4. The elected species was searched and is deemed free of the prior art. Accordingly, the search was expanded as called for under current Office Markush practice - a compound by

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compound search - to include a single additional species. That species is



wherein (in formula (I)) A is piperidine substituted with hydroxyl; X is a single bond; Y is -CO-; Z is -NH-; and B is phenyl. The above species reads on claims 10-16, 44, 46-47, 55 and 57-58. A rejection as to those claims follows. Claims 17, 20, 22, 25, 27, 29-30 and 51-52 are objected to as depending from a rejected claim.

***Claim Rejections - 35 USC § 102***

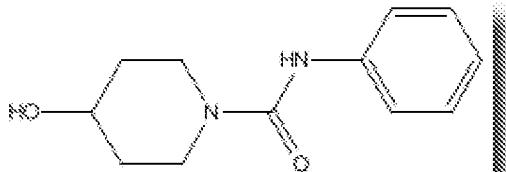
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 10-16, 44, 46-47, 55 and 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ashwell et al (WO 2002/006229)*.**

7. Instant claim 10 is drawn to a compound represented by formula (I) which encompasses



the following compound species  
wherein A is piperidine substituted with hydroxyl; X is a single bond; Y is -CO-; Z is -NH-; and B is phenyl.  
The above species additionally reads on claims 11-16, 44 and 46-47.

8. As evidenced by the attached STN Report (**Accession Number 2002:72044**) *Ashwell et al* teach the above compound species as a reactant, reagent or intermedient in the preparation of  $\beta$ 3-adrenergic receptor agonists. As such, instant claims 10-16, 44 and 46-47 are anticipated.

9. Instant claims 55 and 57-58 are drawn to EDG-5 antagonists comprising a compound according to claim 10 and which encompasses the above identified compound species. Since Applicants indicate that compounds of formula (I) as recited by instant claim 10 (and which encompasses the above identified compound species) are EDG-5 antagonists (Instant Specification, Page 4, Lines 4-15), it is thus asserted that the compound disclosed by *Ashwell et al* would necessarily encompass an EDG-5 antagonist as recited by instants 55 and 57-58. Accordingly, instant claims 55 and 57-58 are also anticipated.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614